DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUN 21 2000

Robert W. Pollock
Vice President
Lachman Consultant Services, Inc.
1600 Stewart Avenue
Westbury, NY 11590

Re: Docket No. 00P-0585/CP1

Dear Mr. Pollock:

This formally responds to your citizen petition, dated February 10, 2000, requesting that the Food and Drug Administration (FDA) determine whether Prozac® (fluoxetine hydrochloride) 20-milligram (mg) tablets were withdrawn from sale for reasons of safety or effectiveness.

The FDA has reviewed its records and has determined that Prozac® (fluoxetine hydrochloride) 20 mg tablets (NDA 20-974) were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, FDA will continue to list Prozac® (fluoxetine hydrochloride) 20 mg tablets in the "Discontinued Drug Product List" section of *Approved Drug Products with Therapeutic Equivalence Evaluations* (the Orange Book).

Enclosed is a copy of the *Federal Register* notice which announces the FDA determination. If you require any further information, please call me at 301-594-2041.

Sincerely,

Carol Drew

Carol Drew
Regulatory Policy Staff
Center for Drug Evaluation and Research

Enclosure

00P-0585

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